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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,353	04/27/2001	Gary Ruvkun	00786/351005	3561

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EXAMINER

KAUSHAL, SUMESH

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,353

Applicant(s)

RUVKUN ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Claims 1-11 were pending and were examined in this office action.

► *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a method for identifying a compound that is capable of decreasing the expression or activity of daf-16 gene in a nematode, or isolated mammalian cell* (election required), classified in class 435, subclass 375.
- II. Claims 5, and 9-10, drawn to a method for identification of a compound that is candidate compound for ameliorating or delaying an impaired glucose tolerance condition comprising screening the compound in a daf-2, daf-16 mutant nematode that express mammalian AFX polypeptide, classified in class 800, subclass 3.
- III. Claims 6, and 9-10, drawn to a method for identification of a compound that is candidate compound for ameliorating or delaying an impaired glucose tolerance condition comprising screening the compound in an age-1, daf-16 mutant nematode that express mammalian AFX polypeptide, classified in class 800, subclass 3.
- IV. Claims 7, and 9-10, drawn to a method for identification of a compound that is candidate compound for ameliorating or delaying an impaired glucose tolerance condition comprising screening the compound in an daf-2, daf-16 mutant

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nematode that express mammalian FKHR polypeptide, classified in class 800, subclass 3.

V. Claims 8, and 9-10, drawn to a method for identification of a compound that is candidate compound for ameliorating or delaying an impaired glucose tolerance condition comprising screening the compound in an age-1, daf-16 mutant nematode that express mammalian FKHR polypeptide, classified in class 800, subclass 3.

VI. Claim 11, drawn to a method of screening compounds that modulates the interaction between the daf-16 polypeptide and a second daf-polypeptide (in-vitro), classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, III, IV and V are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of groups I, II, III, IV and V requires structurally and functionally distinct transgenic nematodes, which have mutations in different daf-genes (daf-2, age-1) and express different mammalian genes (AFX, FKHR). Thus these inventions are distinct and are of separate uses.

Inventions of Groups I and VI are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case the method of group I requires the identification of compounds using a nematode, isolated nematode cell and an isolated mammalian cell that express daf-16 gene (in-situ), whereas the invention of Group VI requires protein-protein interaction. Thus these invention are distinct and are of separate use.

* In order to be perfectly clear, the following Inventions within the particular Groups are NOT species elections. These are independent and distinct Inventions for the reasons given above and a further election of a single Invention from the elected Group is required.

With regard to Groups I the independent and distinct Inventions are as follows:

Invention- i) identifying compound using a nematode or isolated nematode cell.

Invention- ii) identifying compound using a genetically engineered mammalian cell that express daf-16 gene.

With regard to the different Inventions, the method of identifying compounds in a genetically engineered mammalian cell is distinct from a method of identifying a compound in a nematode or isolated nematode cell, since these cells are genetically and functionally distinct from each other. The compounds identified by these methods would be distinct, since the interaction among various cellular components is unique to mammalian or nematode cellular microenvironment. **Applicant is required under 35 U.S.C. 121 to elect a single disclosed Invention.**

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal

Patent examiner



JEFFREY FREDMAN
PRIMARY EXAMINER